

CLAIMS

1. An isolated nucleotide sequence comprising a coding sequence which comprises
- 5 (i) a sequence coding for the promoter activity-regulating polypeptide OrfY as defined herein;
- (ii) a sequence coding for a polypeptide that is at least 15% identical to the sequence of (i)
- 10 and that has at least part of the promoter activity-regulating activity of the OrfY polypeptide;
- (iii) a fragment of (i) or (ii) that codes for a fragment of the polypeptide OrfY that has at least part of the promoter activity-regulating activity of the OrfY polypeptide; or
- 15 (iv) a sequence that is complementary to any of (i) to (iii).
2. A nucleotide sequence according to claim 1 comprising, as the coding sequence, a sequence which includes:
- 20 (i) *orfY* as shown in Table 2; or
- (ii) a fragment thereof that codes for a polypeptide having at least part of the promoter activity-regulating activity of the intact OrfY polypeptide .
- 25 3. A nucleotide sequence according to claim 1 or 2 further comprising a promoter sequence the activity of which is regulatable by the OrfY polypeptide, the polypeptide that is at least 15% identical with OrfY, or a fragment thereof having at least part of the promoter activity-regulating activity of the intact OrfY polypeptide.
- 30 4. A nucleotide sequence according to claim 1 comprising a promoter regulating the expression of any of the coding sequences (i) to (iv) of claim 1 or the coding sequences (i) or (ii) of claim 2.

5. A nucleotide sequence according to claim 4 where the promoter regulating the expression of said coding sequences is a promoter not naturally associated with said sequences.
- 5 6. A vector comprising the nucleotide sequence of claims 1 or 2
7. A vector according to claim 6 which comprises a plasmid, a bacteriophage, a transposable element or a cosmid.
- 10 8. A cell transformed with the nucleotide sequence of claims 1 or 2 or the vector of claim 6.
9. A cell according to claim 8 which comprises a bacterial cell, a fungal cell, a yeast cell, a plant cell, an animal cell or a human cell.
- 15 10. A cell according to claim 9 which is a bacterial cell comprising lactic acid bacterial species.
11. A cell according to claim 10 which is of a *Lactococcus* species.
- 20 12. A method of regulating in a cell the activity of a promoter sequence, the activity of which is regulatable by the OrfY polypeptide or a polypeptide that is at least 15% identical with OrfY and having at least part of the promoter activity-regulating activity of OrfY, or a fragment thereof having at least part of the promoter activity-regulating activity of the
- 25 intact OrfY polypeptide, the method comprising inserting into the cell the nucleotide sequence of claim 1 or 2 and combining it with appropriate expression signals to permit the expression of the coding sequence of said sequence, resulting in the production of an OrfY polypeptide, a polypeptide being at least 15% identical herewith, or a fragment thereof having at least part of the promoter activity-regulating activity of the OrfY
- 30 polypeptide.
13. A method according to claim 12 wherein the promoter sequence is a promoter sequence naturally occurring in the cell.

14. A method according to claim 13 wherein the promoter sequence is a sequence not naturally occurring in the cell.

15. A method according to claim 14 wherein the promoter sequence is of lactic acid
5 bacterial origin.

16. A method according to claim 15 wherein the promoter sequence is P170 as described hereinbefore.

10 17. A method according to claim 12 wherein the promoter sequence comprises a regulatable promoter promoter or a constitutive promoter.

18. A method according to claim 17 wherein the promoter sequence in the cell is a regulatable promoter regulated by a factor comprising pH, the growth temperature, the
15 oxygen content, a temperature shift eliciting the expression of heat chock genes, the composition of the growth medium including the ionic strength/NaCl content, the presence/absence of essential cell constituents or precursors therefor, accumulation of a metabolite intracellularly or in the medium, the growth phase of the cell or the growth rate of the cell.

20 19. A method according to claim 18 wherein the cell is the cell of any of claims 8-11.

20. A method according to claim 12 wherein the activity of the promoter sequence is enhanced by the OrfY polypeptide or the fragment thereof.

25 21. A method of producing a desired gene product, the method comprising constructing a cell that comprises the nucleotide sequence of any of claims 1 or 2 or the vector of claim 6, and a sequence coding for the desired gene product, said coding sequence is under the control of a promoter, the activity of which is regulatable by the OrfY polypeptide or a
30 polypeptide that is at least 15% identical with OrfY, or a fragment thereof having at least part of the promoter activity-regulating activity of OrfY, cultivating the cell under conditions where both of (i) the sequence coding for the OrfY polypeptide or a polypeptide that is at least 15% identical with OrfY, or the fragment thereof having at least part of the promoter activity-regulating activity of the intact OrfY polypeptide and (ii) the sequence coding for

22. A method according to claim 21 wherein the expression of the sequence coding for
5 the OrfY polypeptide or the fragment thereof results in an enhancement of expression of
the desired gene product.

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26. A method according to claim 25 wherein the promoter sequence is a promoter sequence as defined in claim 13.

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formulating the pharmaceutically active product with a composition which includes a cell according to claim 8.

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inserting the biologically and/or pharmaceutically active gene product into a cell according to claim 8.